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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,228	10/28/2005	David W Morris	PP23370.0003/20366-03GUS1	4557
55255 7590 09/17/2009 Novartis Vaccines and Diagnostics, Inc. Corporate Intellectual Property P.O. BOX 8097 EMERYVILLE, CA 94662-8097				
EXAMINER				
HOLLERAN, ANNE L				
ART UNIT		PAPER NUMBER		
1643				
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09/17/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/539,228

**Applicant(s)**

MORRIS ET AL.

**Examiner**

ANNE L. HOLLERAN

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-34, 51, 78, 82-87, 89, 90, 93 and 94 is/are pending in the application.
- 4a) Of the above claim(s) 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51, 78, 82-87, 89, 90, 93 and 94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed 4/29/2009 is acknowledged.

Claims 32-34, 51, 78, 82-87, 89, 90, 93 and 94 are pending. Claims 32-34, drawn to non-elected inventions, are withdrawn from consideration.

Claims 51, 78, 82-87, 89, 90, 93 and 94 are examined on the merits.

#### ***Claim Rejections Withdrawn:***

##### ***Claim Rejections - 35 USC § 112-second paragraph***

The rejection of claims 51 and 94 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

##### ***Claim Rejections - 35 USC § 112-first paragraph***

The rejection of claims 78-80, 82-95 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods where the expression product that is detected is an mRNA having a sequence of SEQ ID NO: 777, does not reasonably provide enablement for methods where the expression product that is detected is an mRNA having a sequence at least 98% identical to SEQ ID NO: 777, 95% identical to SEQ ID NO: 777, or is greater than about 75% in overall homology to SEQ ID NO: 777 is withdrawn upon further consideration.

The rejection of claims 78-81, 82-92, 94 and 95 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn upon further consideration.

The rejection of claims 83-93 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn upon further consideration.

***Claim Rejections - 35 USC § 102***

The rejection of claims 83-87 and 91-93 under 35 U.S.C. 102(e) as being anticipated by Venter (US 6,821,339; issued Nov. 2, 2004; effective filing date is Oct. 20, 2000) is withdrawn upon further consideration.

***Claim Rejections Maintained:***

***Claim Rejections - 35 USC § 112-first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51, 78, 82-87, 89, 90, 93 and 94 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art

to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not reasonably provide enablement for methods of diagnosing any and all cancers, or diagnosing colon, breast or prostate cancer, comprising the active steps of differential detection of expression of a gene which expresses a nucleic acid comprising SEQ ID NO: 777; comprising comparing a level of myosin I mRNA comprising SEQ ID NO: 777 in a patient sample, comprising colon, breast or prostate tissue; comprising detecting evidence of differential expression of myosin I gene which expresses a nucleic acid comprising SEQ ID NO: 777 in a patient sample; or diagnosing colon, breast or prostate cancer in a patient comprising detecting the amount of a duplex formed between a polynucleotide that hybridizes under conditions recited in claim 94 to a nucleotide sequence comprising SEQ ID NO: 777, when contacted with nucleic acids of a patient colon, breast or prostate sample.

Applicants' arguments have been considered, but fail to persuade.

Applicants state that enablement does not require absolute predictability, but that the person of ordinary skill in the art be able to practice the invention without undue experimentation. Applicants discuss the factors set forth in *In re Wands*, at 737 & 738 (*In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)). Applicants point to prophetic teachings in the specification. The passages of the specification characterized as prophetic are those which describe future experiments that might be used to establish that detection of myosin I gene products as they relate to a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 777 will allow one of ordinary skill in the art to diagnose any and all cancers, or diagnose colon, breast or prostate cancer. Applicants state that the methods for detection of expression levels of gene products are known in the art and would not lead to undue experimentation. However, the



Db 1 MetGlySerLysGlyValTyrGlnTyrHisTrpGlnSerHisAsnValLysHisSerGly 20

Applicants appear to base their contention that the claimed methods of diagnosing cancer are enabled because the technique of provirus tagging has identified a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 777 as an oncogene. However, Berns (Berns, A., Arch. Virol., 102: 1-18, 1988) teaches that provirus tagging can uncover gene that contribute to any stage of the tumorigenic process, such as initiation for example (see page 3). Thus, by the time patients have an established tumor, any difference in expression level of a gene identified as a putative oncogene may be gone. Therefore, applicants have not provided a convincing argument that the specification provides one of ordinary skill in the art with a reasonable expectation of success in using the detection of myosin I gene expression for the diagnosis of any and all cancers.

### *Conclusion*

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR



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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
September 14, 2009

/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643